



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-3427, CMS-10709, CMS-10631 and CMS-10466]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: OIRA_submission@omb.eop.gov

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

1. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

2. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes

agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease Application and Survey and Certification Report; *Use:* Part I of this form is a facility identification and screening measurement used to initiate the certification and recertification of ESRD facilities. Part II is completed by the Medicare/Medicaid State survey agency to determine facility compliance with ESRD conditions for coverage. *Form Number:* CMS–3427 (OMB control number: 0938–0360); *Frequency:* Every three years; *Affected Public:* Private sector (Business or other for-profit and Not-for profit institutions); *Number of Respondents:* 7,493; *Total Annual Responses:* 2,473; *Total Annual Hours:* 824. (For policy questions regarding this collection contact Jennifer Milby at 410-786-8828).

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Hospital Survey for Specified Covered Outpatient Drugs (SCODs); *Use:* In the CY 2018 OPPS/ASC payment system final rule with comment period, CMS finalized a policy to adjust payment for separately payable outpatient

drugs acquired by eligible hospitals at discounted rates under HRSA's 340B program from Average Sales Price (ASP) plus 6 percent to ASP minus 22.5 percent. According to 42 U.S.C. § 256b, eligible hospitals include those with a Medicare Disproportionate Share Hospital adjustment of greater than 11.75 percent, Children's Hospitals, Critical Access Hospitals, Cancer Hospitals, Rural Referral Centers and Sole Community Hospitals. The 340B program sets a ceiling on the price that covered entities pay for outpatient drugs. The 340B ceiling price refers to the maximum amount that a manufacturer can charge a covered entity for the purchase of a 340B covered outpatient drug. The 340B ceiling price is statutorily defined as the Average Manufacturer Price (AMP) reduced by the rebate percentage, which is commonly referred to as the Unit Rebate Amount (URA).

On December 27, 2018, the United States District Court for the District of Columbia ruled that the Secretary of the Department of Health & Human Services exceeded his statutory authority to adjust payment rates under the Hospital Outpatient Prospective Payment System (OPPS) for separately payable, 340B-acquired drugs. See *American Hospital Ass'n v. Azar*, 348 F. Supp. 3d 62, 82-83 (D.D.C. 2018), appeal pending, Nos. 19-5048 & 19-5198 (D.C. Cir.). The Court reasoned, in part, that the Secretary had not collected the necessary data to set payment rates based on acquisition costs. The government disagrees with that ruling and has appealed. Nonetheless, in the event that the ruling is affirmed, CMS believes that it is important to begin obtaining acquisition costs for specified covered outpatient drugs to set payment rates based on cost for 340B-acquired drugs when they are furnished by certain covered entity hospitals.

The acquisition cost data hospitals submit in response to this survey will be used to help

determine payment amounts for drugs acquired under the 340B program. We want to ensure that the Medicare program pays for specified covered outpatient drugs purchased under the 340B program at amounts that approximate what hospitals actually pay to acquire the drugs. This will ensure that the Medicare program uses taxpayer dollars prudently while maintaining beneficiary access to these drugs and allowing beneficiary cost-sharing to be based on the amounts hospitals actually pay to acquire the drugs. Form Number: CMS-10709 (OMB control number: 0938-New); Frequency: Occasionally; Affected Public: Business or other for-profits and Not-for-profits, State, Local, or Tribal Governments; Number of Respondents: 1,338; Total Annual Responses: 1,338; Total Annual Hours: 64,224. (For policy questions regarding this collection contact Steven Johnson at 410-786-3332.)

3. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* The PACE Organization Application Process in 42 CFR Part 460; *Use:* The Programs of All-Inclusive Care for the Elderly (PACE) consist of pre-paid, capitated plans that provide comprehensive health care services to frail, older adults in the community who are eligible for nursing home care according to State standards. PACE organizations (PO) must provide all Medicare and Medicaid covered services; financing of this model is accomplished through prospective capitation of both Medicare and Medicaid payments. Upon approval of a PACE application, CMS executes a 3-way program agreement with the applicant entity and the applicable State Administering Agency (SAA). CMS regulations at 42 CFR 460.98(b)(2) require a PO to provide PACE services in at least the PACE center, the home, and inpatient facilities. The PACE center is the focal point for

the delivery of PACE services; the center is where the interdisciplinary team (IDT) is located, services are provided, and socialization occurs with staff that is consistent and familiar to participants.

Collection of this information is mandated by statute under sections 1894(f) and 1934(f) of the Act and at 42 CFR part 460, subpart B, which addresses the PO application and waiver process. In general, PACE services are provided through a PO. An entity wishing to become a PO must submit an application to CMS that describes how the entity meets all the requirements in the PACE program. An entity's application must be accompanied by an assurance from the SAA of the State in which the PO is located.

CMS recently issued a final PACE rule (CMS-4168-F), effective August 2, 2019, which updates and modernizes the PACE program. This final rule codifies CMS' existing practice of relying on automated review systems for processing initial applications to become a PACE organization and expansion applications for existing PACE organizations. In addition, the final rule will modify the PACE regulations to eliminate the need for PACE organizations to request waivers for a number of the most commonly waived provisions. This latter change is expected to reduce burden and improve efficiency for POs, state administering agencies, and CMS.

In addition to codifying the current automated processes for the submission and review of both initial and service area expansion applications, this rule modifies existing regulatory provisions and requirements. As a result, certain attestations associated with the application are no longer applicable, and others need to be updated to reflect updated regulatory requirements. We are also making minor tweaks to certain document upload requirements for clarification

purposes based on experience reviewing applications. *Form Number*: CMS-10631 (OMB control number: 0938-1326); *Frequency*: Yearly; *Affected Public*: State, Local, or Tribal Governments; *Number of Respondents*: 72; *Total Annual Responses*: 109; *Total Annual Hours*: 7,226. (For policy questions regarding this collection contact Debbie Vanhoven at 410-786-6625.)

4. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; *Use*: The data collection and reporting requirements in “Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions” (78 FR 39494 – July 1, 2013)), address federal requirements that states must meet with regard to the Exchange minimum function of performing eligibility determinations and issuing certificates of exemption from the shared responsibility payment. In the final regulation, CMS addresses standards related to eligibility, including the verification and eligibility determination process, eligibility redeterminations, options for states to rely on HHS to make eligibility determinations for certificates of exemption, and reporting. *Form Number*: CMS-10466 (OMB control number: 0938-1190); *Frequency*: Occasionally; *Affected Public*: Private Sector (Businesses or other for-profits); *Number of Respondents*: 45,060; *Total Annual Responses*: 45,060; *Total Annual Hours*: 12,150. (For policy questions regarding this collection contact Katherine Bentley at 301-492-5209.)

Dated: February 3, 2020

William N. Parham, III

Director, Paperwork Reduction Staff

Office of Strategic Operations and Regulatory Affairs

4120-01-U-P

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